MAY 19 2008

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A Software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

February 12, 2008

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A Software

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
MHX	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025
DSF	Paper Chart Recorder	870.2810

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05and L-ICU05A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU02 and L-ICU02A software (K021376).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The two software options for the S/5™ Critical Care Monitor are identical, except that the L-ICU05A is equipped with extended arrhythmia analysis capability. There are two monitor frame options; the new 5-module F-CU5(P) monitor frame and the 8-module F-CU8 monitor frame which can be extended with an Extension Frame, F-EXT4, via the Extension Module E-EXT. The monitor can be equipped with a Recorder Module, E-REC. The S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A uses several types of plug-in measurement modules. The legacy Datex-Ohmeda M-series measurement modules can be used but they have been replaced by the new E-series modules (510(k)'s submitted separately), which are basically face-lifted versions of the corresponding M-series modules. Modules (with the exception of E-REC and E-EXT) are the subject of separate 510(k)'s and are not part of this notification. The S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the S/5™ monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin. The S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter. The S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™. The software L-ICU05 and L-ICU05A perform some module related tasks like arrhythmia analysis, ST–values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis evoked potential response averaging and entropy calculations. All the module communication is also handled in the main software. There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (REMCO) which is still directly connected to the S/5™ Critical Care Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. To facilitate quick access to menus, a bar code reader is also supported, although the bar code reader is not manufactured anymore.

The S/5™ Critical Care Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends can be sent via a network to a central computer for archiving.

The S/5 Critical Care monitor can also be upgraded to L-ICU05(A) software using the S/5 L.I.F.E. upgrade program that offers a means to continuously keeping products up-to-date, by upgrading modular anesthesia and critical care monitors and network products dating from back to 1992 to the latest S/5 software level. Upgrading of modular monitors and network products is performed with one of the available U-LIFE upgrade kits. The kit includes all hardware and software components needed to make the monitor or network product compatible with the latest main software being delivered.

INTENDED USE as required by 807.92(a)(5)

Intended Use:

The S/5™ Critical Care Monitor with L-ICU05and L-ICU05A is intended for multiparameter patient monitoring.

Indications for use:

The S/5 Critical Care Monitor with L-ICU05 and L-ICU05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, and neurophysiological status of all patients.

When the BIS module is used with the S/5 Critical Care Monitor with L-ICU05 and L-ICU05A, it is intended for use by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The Bispectral index (BIS), a processed EEG variable, and one component of the BIS measurement, may be used in adults as an aid in monitoring the effects of certain anesthetic agents. The Bispectral index is a complex technology, intended for use only as an adjunct to clinical judgement and training. In addition, the clinical utility, risk/benefit, and application of BIS have not undergone full evaluation in the pediatric population.

The S/5 Critical Care Monitor with L-ICU05 and L-ICU05A software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05and L-ICU05A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU02 and L-ICU02A software (K021376). The S/5™ Critical Care Monitor with L-ICU05and L-ICU05A is a modular multiparameter patient monitor providing connections to measurement modules. The general construction, intended use of the S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A are the same as for the predicate S/5™ Critical Care Monitor with L-ICU02 and L-ICU02A software (K021376). The indications for use for the Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05and L-ICU05A software are the same as for the predicate.
The S/5™ Critical Care Monitor with L-ICU05and L-ICU05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients. The S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents. The S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A software is indicated for use by qualified medical personnel only. Based on the above and a detailed analysis in the Comparison document and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A software is substantially equivalent to the predicate S/5™ Critical Care Monitor with L-ICU02 and L-ICU02A software (K021376).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A Software has been assessed against the standards below and details of conformity are presented in the attached 510(k) notification. The device has been thoroughly tested through validation and verification of specifications.

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1999/EN 60601-2-30:2000
- IEC 60601-2-34:2001/EN 60601-2-34:2000
- IEC 60601-2-40:1998
- IEC 60601-2-49:2001
- IEC 60601-1-2(2001)/EN 60601-1-2
- IEC 60601-1-4: 1996+Amdt. 1:1999/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- ISO 11196:1995 + Corr. 1:1997/EN ISO11196:1997
- IEC 601-2-10:1987/EN 60601-2-10:2000 + Amd.1:2001
- IEC 60601-2-26:2002/EN60601-2-26
- EN 1060-1:1995 / EN-1060-3:1997
- EN 12470-4:2000
- IEC 60068-2
- UL 2601-1:1997
- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

CONCLUSION:

The summary above shows that the Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A Software is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU02 and L-ICU02A software (K021376).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2008

GE Healthcare
c/o Mr. Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K071889
Trade/Device Name: Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05 and L-ICU05(A) Software
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: April 18, 2008
Received: April 21, 2008

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071889

Device Name: **Datex-Ohmeda S/5™ Critical Care Monitor with L-ICU05 and L-ICU05A software.**

Indications for use:

The S/5 Critical Care Monitor with L-ICU05 and L-ICU05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, and neurophysiological status of all patients.

When the BIS module is used with the S/5 Critical Care Monitor with L-ICU05 and L-ICU05A, it is intended for use by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The Bispectral index (BIS), a processed EEG variable, and one component of the BIS measurement, may be used in adults as an aid in monitoring the effects of certain anesthetic agents. The Bispectral index is a complex technology, intended for use only as an adjunct to clinical judgement and training. In addition, the clinical utility, risk/benefit, and application of BIS have not undergone full evaluation in the pediatric population.

The S/5 Critical Care Monitor with L-ICU05 and L-ICU05A software is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071889